

Vaccine Management Standard Operating Procedure (SOP) sample

Purpose: To ensure the safe storage and handling of vaccines to maintain optimum potency.

Instructions:

- Review and update document annually, when vaccine management policies change, and when staff with designated vaccine management responsibilities change.
- All staff handling vaccines must adhere to the protocols described in this document.
- Post on or near vaccine storage unit(s).

Important Contacts

Office/Practice Name	Pin Number:
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Role	First and Last Name	Phone #	Email
Primary Vaccine Coordinator			
Back-Up Vaccine Coordinator			

*Notify the Vaccine Unit within 10 days if a new Primary Vaccine Coordinator or Backup is identified.

Emergency Vaccine Storage Location

Storage Location	Address and City	Contact Name	Contact Phone #	Alt Phone #	Email

Vaccine Storage & Handling

- Refrigerators/freezers designated for vaccine storage are required to maintain the proper temperature **Pharmaceutical-grade refrigerators are required for ALL storage unit** for all facilities that administer at least some vaccines to those <19 years of age, excluding sites that only administer flu vaccine. This requirement applies to all secondary and temporary units.
- **The use of any household combination refrigerator/freezer unit for storage of any vaccines including temporary storage is strictly prohibited.**
- Refrigerated vaccines should be stored within the temperature range of 2° C to 8° C in a **Pharmaceutical-grade** refrigerator designated for vaccine storage only.
- Varicella and MMRV vaccine must be stored in a stand-alone freezer that maintains a temperature between -50°C and -15° C. Store **MMR vaccine in the freezer** to reduce the likelihood of a vaccine loss due to a refrigeration issue.
- Do not store anything on top of the storage unit which could prevent the door from completely closing.
- Rotate stock ensuring that short-dated vaccine is used first.
- Mark or identify inventory to differentiate state-supplied and privately purchased vaccine.
- Place the digital data logger probe in a central area of the refrigerator and freezer unit affixing it to the shelf, adjacent to the vaccine.
- Do not store food or beverages in vaccine storage units.
- Store vaccines centrally in the refrigerator or freezer, and away from walls to allow for proper air circulation. There should be sufficient space between rows of vaccine boxes or bins and shelving units to allow proper air circulation. Do not over crowd refrigerators, especially during flu season.
- Store cold/gel packs in the refrigerator as part of your emergency preparedness, in case the need arises to transport vaccine during an emergency.
- Stabilize freezer temperatures by placing freezer packs where there is empty space.
- Post a "DO NOT UNPLUG" sign next to the electrical outlet for all vaccine storage units and a "DO NOT DISCONNECT" sign must be posted next to the circuit for any vaccine storage units on the circuit breaker.

- Plug all vaccine storage units directly into a wall outlet. Check with electrician to see if a 'dedicated line' is needed for your refrigerator(s). Never plug storage units into power strips, surge protectors or use extension cords. Never plug storage units into Ground Fault Circuit Interrupter outlets (GFC).

Temperature Monitoring

- Monitor and document temperatures using a Digital Data Logger only. The digital data logger must have a calibrated glycol-encased probe and be certified by an appropriate agency (e.g. National Institute of Standards and Technology). Please contact the Vaccine Unit to replace broken MDPH-supplied thermometers.
- Monitor refrigerator/freezer daily minimum and maximum temperatures and acknowledge twice daily by **pressing the read button on the Fridge Tag 2L data logger 4x in AM and 2x in PM**. Other monitoring systems must have this capability and will need prior authorization to be used by the MDPH Vaccine Unit. A Certificate of calibration must be kept on file. All vaccine storage units holding state-supplied vaccines must be monitored by a digital data logger.
- Review temperature logs or digital data logger digital read outs at least once a day for any deviations from recommended temperature ranges. If your state-supplied data logger is broken, call the Vaccine Unit for immediate replacement.

Vaccine Receiving

- Staff receiving shipments (front office, loading dock, reception, etc.) must notify the Primary Vaccine Coordinator or backup as soon as a vaccine shipment arrives.
- Open shipping container immediately upon arrival. Check the two transit temperature monitors for those shipments sent from McKesson. If temperature monitors indicate a possible temperature variation, the Primary Vaccine Coordinator will contact McKesson Specialty at (877) 822-7746 by the end of the day.
- For direct ship vaccines from Merck, check the shipment date located on the packing list and check the shipper insert supplied in the box. Varicella shipments can be sent in a 2 day or 4 day box. MMRV shipments are always shipped in a 24 hour box. Contact Merck Order Management Center by the end of the day of receipt at 800-637-8579 if date received is greater than the shipper insert indicates.
- MMRV and Varicella vaccine never arrive in the same shipping container.
- Count vaccines in shipment and compare with packing list and original order to make sure the order and delivery is correct. Check to ensure that expiration dates and lot numbers match. Make sure diluent is also accounted for.
- Ensure that all containers noted on the packing list have been delivered.
- Place vaccine in the refrigerator/freezer designated for vaccine storage immediately after an inventory of the shipment is completed.
- Contact the Vaccine Unit immediately for guidance if there are any concerns or inaccuracies with the vaccine order.

Vaccine Transportation Procedures

- Contact the Vaccine Unit whenever you are considering transporting state-supplied vaccines outside of your facility to ensure you have the most relevant guidance and advice for your specific situation.
- Obtain and store an adequate number/amount of appropriate packing containers and materials (e.g., frozen and refrigerated gel packs, bubble wrap) needed to pack vaccines for safe transport.
- Use separate packing containers for vaccines required to be refrigerated and vaccines required to be frozen. Label outside of packing container 'Must Store in Refrigerator' or 'Must Store in Freezer'.
 - Refrigerated gel packs should be placed in the container used to transport refrigerated vaccines. Separate the vaccine from the cold packs with cardboard and /or bubble wrap.
 - Frozen gel packs should be placed in the container to transport frozen vaccines. **(Dry ice is not recommended for the transport of frozen vaccines. It is too cold.)**
- Place a calibrated thermometer in each packing container near the vaccine to monitor the temperatures.
- Record the time and temperature when vaccine was removed from the storage units and placed in the containers at the beginning and end of the transport on the Trouble Shooting log.

- Transport of vaccines is considered a temperature excursion
 - Contact the Vaccine Unit with the amount of time that vaccine was out of a refrigerator or freezer and the warmest and coldest temperatures recorded.
- Do not discard vaccine without contacting the Vaccine Unit for guidance.

Vaccine Ordering and Inventory Control

- Place vaccine orders through the MIIS Vaccine Management Module and upload the most recent temperature logs for all vaccine storage units within one day of submitting order.
 - Upload all temperature logs monthly if not placing monthly vaccine orders. Data loggers only hold 56 days of temperatures.
- Complete a physical inventory of all vaccines in the refrigerator(s) and freezer(s), checking expiration dates at least monthly and before placing an order.
- Order when vaccine inventories reach about a 4 week supply.
- Establish a routine to order no more than once per month.
- Contact the Vaccine Unit to update any changes in shipping address. Changes to shipping hours or shipping contact can be updated directly into the MIIS. Vaccines will be delivered directly to this provider's office based on shipping information in the MIIS.
- Transfer short dated vaccines to another pediatric provider 2-3 months prior to expiration. Document all vaccine transfers in the MIIS Transfer Vaccine Module.

Vaccine Returns

- **Only the Vaccine Management Unit can determine loss of efficacy due to exposure to out of range temperatures.**
- Document all vaccines that cannot be used due to expiration, exposure to unsafe temperatures or vaccines that are wasted/damaged in the New Order Module or the Storage/Handling Problem Module. Refer to the [Quick Reference Guide](#) for instructions.
- Pack vaccine in a box with the return form. A return label will either be e-mailed or UPS will provide a label at time of pick up.
- Do not return broken vials or syringes, opened multi dose vials or vaccine drawn up into a syringe. Make sure these doses are documented in the MIIS.

Temperature Out of Range

- Immediately contact the Vaccine Unit for guidance about any out of range temperatures (refrigerator or freezer). Upon discovery of an out of range temperature, the exposed vaccine must be maintained at proper temperature and marked 'Do Not Use'. Vaccine Unit staff will determine if the vaccine is still viable for use. Upload temperature logs into the MIIS and select 'Urgent Temperature Log Issue' and immediately call the Vaccine Unit.
- Mark any vaccine left out of a storage unit 'Do Not Use,' put the vaccine back into the appropriate storage unit, and call the Vaccine Unit for guidance.
- Use [trouble shooting log](#) to document out of range temperatures, contact with the Vaccine Unit and actions taken.
- Remove any vaccine determined by the Vaccine Unit to be damaged, from the storage unit.

Power Failure/Refrigerator Failure

- Pack vaccines in insulated containers with cool packs and a certified, calibrated product thermometer and transport to secure refrigerators in the event of an extended building power failure or refrigerator failure. See Emergency Storage location at the top of page 1. The above temperature ranges and monitoring procedures will be followed at the back-up site. Notify the Vaccine Unit immediately, or as soon as possible. Consult the Vaccine Unit before transporting Varicella and MMRV vaccine, if possible.
- Review and update the provider emergency plan on an annual basis.

Documentation

- Enroll annually in the MDPH Immunization Program/Vaccines for Children (VFC) program by completing online enrollment in the MIIS Provider Enrollment Module.
- Review and update the SOP annually and when any changes occur.
- Retain a record of vaccines received or transferred, including type of vaccine, manufacturer, lot number, expiration date and number of doses, for a minimum of 3 years. Keep packing slip received in shipments from both McKesson and Merck. If your site is registered with the MIIS and has access to the Vaccine Management Module, this requirement is fulfilled and there is no need to retain paper copies.
- Maintain temperature logs for a minimum of 3 years. There is no need to retain paper copies if *EVERY* temperature log for all vaccine storage units is uploaded into the MIIS monthly.
- Offer the appropriate Vaccine Information Statement (VIS) with each dose of vaccine administered. Subscribe to the CDC's e-mail update for VIS at: www.cdc.gov/vaccines/hcp/vis/index.html.
- Record vaccine administration information in the patient's chart including: administration date, type of vaccine, manufacturer, lot number, expiration date, date on VIS, date VIS is given, name and title of person administering the vaccine.
- Report all state supplied doses administered in the MIIS Vaccine Management Module with each vaccine order. Most EHRs are connected so that the dose will decrement from inventory and appear in your usage report as immunizations are given and documented.

Staff Training/Provider education requirements

- The Primary Vaccine Coordinator and the Backup Vaccine Coordinator will participate in one of the following activities each year. Certificates of completion must be kept on file.
 - VFC compliance site visit (conducted every other year, must be present at site visit to receive certificate).
 - In-person classroom style presentation (VFC breakout session at MIAP, MDPH Immunization Update Conference, or on-site training by MDPH staff). Certificates will be given after each activity.
 - MDPH on-line webinar trainings.

Go to the training page of the MIIS Resource Center, www.contactmiis.info, to view training materials, Quick Reference Guides and Webinars about the MIIS.

ALL STAFF WHO ADMINISTER VACCINES, MONITOR STORAGE UNIT TEMPERATURES OR WHO MAY TRANSPORT VACCINE IN AN EMERGENCY MUST READ THIS SOP IN ITS ENTIRETY, SIGN AND DATE THIS DOCUMENT

This SOP was created by (name and title): _____

Review Date: _____

Date	Employee Name

Staff Training on VFC Requirements for Vaccine Coordinator and Back-Up Vaccine Coordinator, including proper vaccine storage and handling.		
Date	Employee Name	Training Type